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THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			EXAMINER JEAN-LOUIS, SAMIRA JM	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,509	Applicant(s) COELINGH BENNINK ET AL.
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 05 June 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-32 is/are pending in the application.
 4a) Of the above claim(s) 17,21-23,25,27 and 29-31 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 18-20, 24, 26, 28, and 32 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Arguments

This Office Action is in response to the amendment submitted on 06/05/09.

Claims 17-32 are currently pending in the application, with claims 17, 21-23, 25, 27, and 29-31 having been withdrawn. Accordingly, claims 18-20, 24, 26, 28, and 32 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the amendment of claim 28 wherein "preventing" is replaced with the term "reducing the risk of developing" has been fully considered but is not found persuasive. While applicant recited the limitation of a method of treating or preventing vaginal dryness, nowhere in the specification did applicant recite a method of reducing the risk of developing vaginal dryness. Rather, in the instant specification, applicant recites a method that is applied to human skin which is already dry, flaky, lined, wrinkled, aged, photodamaged, or to healthy skin to prevent or reduce such deterioration changes (i.e. reducing the dry, flaky, lined, wrinkled, aged and photodamaged skin; see pg. 3, lines 8-15). The Examiner contends that such recitation does not provide support for reducing the risk of developing vaginal dryness. Nonetheless, given that applicant has deleted the term "preventing", the rejection of claims 18-19, 24, 26, 28, and 32 is withdrawn.

Applicant's contention that Kragie in view of Willhite and Sitruk-Ware in view of Spicer and in further view of Willhite does not render obvious applicant's invention as there was no reasonable expectation that estetrol would be pharmacologically useful and that such property of estetrol has been fully considered but is not found persuasive. The examiner especially disagrees because Kragie teaches compositions and methods that can replace the role of estrogens in the functions of humans (see abstract and paragraph 0013). Kragie further teaches the use of Estrogen Function Replacement Agents (EFR) and cites the use various EFR agents including estetrol (i.e. applicant's elected species in claim 28; paragraphs 0038-0039). Additionally, Kragie teaches that the EFR agent would be dosed to provide sufficient biological activity for the desired estrogen function at the tissue target and at a dosage that would minimally meet the EC50 value of the desired estrogenic function (see paragraph 0044). Moreover, Kragie teaches that weak (i.e. less potent) estrogenic compounds can be used and can possess both partial agonist and partial antagonist characteristics (paragraph 0044). Additionally, Kragie teaches the use of the EFR agents for various clinical conditions including treatment of vaginal atrophy and relief of urogenital atrophy (see paragraph 0073). As a result, the Examiner contends that it would have been well within the purview of the skilled artisan to utilize and to try estetrol since Kragie teaches the use of estetrol as an EFR agent in the treatment of vaginal atrophy and urogenital atrophy and given the teaching of Kragie that weak EFR agent can be used at the appropriate dosage in order to provide sufficient biological activity for the desired estrogen function at the target site. Thus, regardless if Kragie teaches a list of EFR agents, the Examiner

maintains that it would have indeed been obvious to try estetrol given that Kragie teaches its use for the treatment of vaginal atrophy and urogenital atrophy and given that Kragie listed a finite number of predictable EFR agents. The Examiner further maintains that Kragie did envisage the use of weak EFR agents such as estetrol since Kragie clearly teaches using weak EFR agents and further discloses that appropriate dosage would be dosed in order to provide sufficient biological activity for the desired estrogen function. Thus, the Examiner maintains that estetrol was indeed taught by Kragie to be used for vaginal dryness and that Kragie did indeed envision EFR and thus estetrol. Willhite et al. were provided to demonstrate that urogenital atrophy is also known as vaginal dryness. As a result, Kragie in view of Willhite does indeed render obvious applicant's invention.

Applicant's argument with respect to claim 20 that requires a ring carrying substituents R1, R2, R3, and R4 comprising three unsaturated bonds and that R6 and R7 are each independently represented by a hydroxyl group, an O-acyl group has been fully considered. Applicant further argues that given that dehydroandrostenedione nor 15- α -hydroxyandrostenedione do not meet these requirement, Younglai does not render claim 20 obvious. Such arguments are not found persuasive since claim 20 is directed to precursors that are derivatives of estetrol (E4) capable of liberating estetrol wherein one of the hydroxyl group has been replaced by an acyl radical of a hydrocarbon carboxylic. The Examiner respectfully points out that the claims do not require R1, R2, R3, and R4 to be OH or addition of three unsaturated bonds. The reference is to the

Art Unit: 1617

precursors as delineated in claim 28 and the sole requirement for such recitation is that the precursors are capable of liberating estetrol. Younglai clearly teaches that 15- α -hydroxyandrostenedione is a precursor of estetrol (see pg. 1616, right col., paragraph 1). Figure 2 clearly teaches that 15- α -hydroxyandrostenedione is a derivative of E4 and contains an acyl group at the R7 position. Consequently, the examiner maintains that Younglai does indeed render claim 20 obvious.

Applicant's argument with respect to Sitruk-Ware who does not render obvious applicant's invention and that Spicer provides no reason to pick estetrol from a long list of a mere possibility has been fully considered. Sitruk-Ware teaches that urogenital symptoms is due to low estrogen after menopause. Sitruk-Ware further teaches that such urogenital symptoms leads to urogenital atrophy, vaginal irritation, and vaginal dryness and suggests the use of estrogen and estrogen compounds to be applied to the vaginal surface to treat such symptoms. Sitruk-Ware does not specifically teach estetrol as the estrogen compound. Spicer teaches the use of estrogenic compounds to counteract the effect of urogenital atrophy. Importantly, Spicer teaches a finite number of estrogenic compounds that can be used in the treatment of urogenital atrophy including estetrol. Consequently, the Examiner maintains that it would have been obvious to use and to try estetrol since Spicer specifically teaches that estetrol may be employed. Thus, regardless of the binding affinity of estetrol, one of ordinary skill in the art would have indeed found it obvious to try estetrol since Spicer clearly teaches estetrol as an estrogenic compound that can exert estrogenic effect.

As for applicant's arguments that one of ordinary skill in the art would not select estetrol as there would be no expectation of success, the Examiner disagrees as Spicer clearly teaches that estetrol can be employed as an estrogenic steroid and thus one of ordinary skill in the art would have indeed found it obvious to try estetrol. Moreover, given that Kragie teaches the use of weak estrogen compounds including estetrol and given Kragie's suggestion to use appropriate dosage of estrogen compounds in order to exert the requisite biological activity, one of ordinary skill in the art would have indeed found it obvious to try estetrol in the correct dosage with reasonable expectation that estetrol would produce the requisite biological estrogenic activity.

While applicant implies(via reference citations and Declarations) that the prior art would not suggest the use of estetrol as estetrol was not found to be pharmacologically useful, the Examiner cites the fact that Kragie explicitly teaches estetrol as an EFR agent. Kragie further teaches appropriate dosages of the EFR agents in order to provide useful estrogenic biological activity and this further suggests that Kragie did indeed envision that the EFR agents would be expected to function as estrogenic compounds. Moreover, Kragie further stated that the EFR agents could be full or partial agonists and thus the Examiner contends that estetrol was indeed envisioned by Kragie as an estrogen agonist that could produce estrogen biological activity. Regarding applicant's arguments that applicant discovered an unexpected pharmacological effect, the Examiner disagrees with such assertion as Holinka et al. (see Holinka, abstract) teaches E4 as a weak estrogen with short duration effects. Thus, in view of Kragie who teaches the use of EFR agents that are partial or full estrogen agonists and in light of

the disclosure of Holinka et al., one of ordinary skill in the art would have indeed found it obvious to try estetrol for the clinical indications taught by Kragie. As a result, the examiner maintains that the pharmacological utility purported by applicant is not unexpected and Kragie in view of Willhite render obvious applicant's invention.

For the foregoing reasons, the 112, first paragraph is withdrawn however the 103(a) rejections of record under 103 (a) remain proper. However, in view of applicant's amendment, the following 112, first paragraph and modified 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor or carrying out his invention.

Claims 18-20, 24, 26, 28, and 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While applicant recited the limitation of a method of treating or preventing vaginal dryness, nowhere in the specification did applicant recite a method of reducing the risk of developing vaginal

Art Unit: 1617

dryness. Rather, in the instant specification, applicant recites a method that is applied to human skin which is already dry, flaky, lined, wrinkled, aged, photodamaged, or to healthy skin to prevent or reduce such deterioration changes (i.e. reducing the dry, flaky, lined, wrinkled, aged and photodamaged skin; see pg. 3, lines 8-15). The Examiner contends that such recitation does not provide support for reducing the risk of developing vaginal dryness. Consequently, due to this lack of written description, the method of reducing the risk of developing vaginal dryness being claimed by applicant cannot be fully ascertained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-19, 24, 26, 28 and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kragie (U.S. 2004/0192598 A1, previously cited) in view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Kragie teaches the use of compositions that can replace the role of estrogens in the functions of humans (see abstract). According to Kragie, the compositions comprise estrogen function replacement agent (s) (EFR) that can selectively, partially, or totally replace the function of estrogens, such as estradiol, in the functions of humans and animals (see pg. 2, paragraph 0013 and pg. 4, paragraph 0033). Examples of such agents include derivatives of estradiol such as estetrol (i.e. a compound of the aforementioned formula which reads on claim 28; see pg. 4, paragraph 0038 and pg. 11, claim 7). The dosage of the EFR is provided for sufficient biological activity for the desired estrogen function at the tissue target and needs to minimally meet the EC50 value (half maximal efficacy concentration; instant claim 24) for the desired estrogen function (see pg. 5, paragraph 0044) and can be administered with a suitable carrier (see pg. 6, paragraph 0051). Kragie further teaches that the compositions may be formulated for topical or transdermal applications in the form of lotions, gels, or creams

and when applied as a transdermal patch for a period of 1 to 4 days wherein the patch contacts the active ingredient to a smaller surface area allowing a slow and constant delivery of the active ingredient (i.e. application more than once a day; instant claims 26 and 32; see pg. 6, paragraph 0051). Of interest, Kragie described the EFR agents containing compositions as useful for menopause and further teach that EFR agents are currently used in perimenopausal and post-menopausal women for treatment of vaginal atrophy and urogenital atrophy (see pg. 8, paragraph 0073).

Kragie does not particularly teach a method of treating vaginal dryness using at least 5 µg/g of estetrol.

However, to one of ordinary skill in the art, it would have been obvious to optimize the appropriate dosage that would produce the desired estrogenic function.

Moreover, it is generally noted that differences in concentration or range do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or dosages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide

the motivation to determine where in a disclosed set of ranges is the optimum combination of dosages.

Willhite et al. have been provided to demonstrate that urogenital atrophy is also known as vaginal dryness (see Introduction Section). Consequently, Kragie necessarily meets the limitation of claim 28 and teaches a method of treating vaginal dryness.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize the method of Kragie with a desired amount of estetrol in the treatment of vaginal dryness since Kragie teaches the use of estradiol derivatives such as estetrol in amounts that would produce the desired estrogenic function for the treatment of urogenital atrophy. Given that Kragie teaches the use of ERF agents to treat urogenital atrophy (i.e. vaginal dryness as disclosed by Willhite et al.) using ERF agents such as estetrol, one of ordinary skill would have been motivated to utilize and try estetrol to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in treating vaginal dryness and efficacious in producing desirable estrogenic function.

Claim 20 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Kragie (U.S. 2004/0192598 A1, previously cited) in view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited) as applied to claims 18-19, 24, 26, 28, and 32 and in further view of Younglai et al. (J.

of Clinical Endocrinology and Metabolism, 1968, Volume 28, Issue 11, pgs. 1611-1617, previously cited).

The Kragie and Willhite references are as discussed above and incorporated by reference herein. However, Kragie and Willhite do not teach the precursors of the estrogenic compound of claim 28 containing acyl radical moieties.

Younglai et al. teach that estetrol (i.e. E4) has many precursors (see pg. 1617, figure 2). In fact, Younglai et al. teach 15- α -hydroxyandrostenedione or dehydroxyandrostenedione as precursors of E4 and containing acyl moiety group (instant claim 20).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize dehydroxyandrostenedione and 15- α -hydroxyandrostenedione as precursors of E4 since Younglai et al. teach them as precursors of E4. Given the teachings of Kragie, Willhite, and Younglai, one of ordinary skill would have been motivated to utilize estetrol derived from 15- α -hydroxyandrostenedione or dehydroxyandrostenedione to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in treating vaginal dryness and efficacious in producing desirable estrogenic function.

Claims 18-19, 24, 26, 28, and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sitruk-Ware et al. (Shweiz. Rundsch. Med. Praxis, 1997, Vol. 86, No. 33, pgs. 1-13, English Translation) in view of Spicer (U.S. 5,211,952, previously cited) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited).

Sitruk-Ware et al. teach that urogenital symptoms is due to low estrogen after menopause (see pg. 2, paragraph 1). This low estrogen is further taught to lead to urogenital atrophy, vaginal irritation and vaginal dryness wherein Sitruk-Ware et al. suggest the use of estrogen to be applied to the vaginal surface to treat such symptoms (see pg. 2, paragraphs 2-3, pg. 3, paragraph 2, and pg. 4, paragraph 2). Sitruk-Ware et al. further teach that estrogenic treatment at doses necessary for making the symptoms disappear is an efficient way to correct the aforementioned symptoms (see pg. 2, paragraphs 2-4, pg. 4, paragraph 2, and pg. 10, paragraph 2). Different modes of application have been developed including vaginal creams (instant claim 32, pg. 2, last paragraph). Sitruk-Ware et al. further teach that treatments with low adverse effects and low doses are preferred (pg. 10, paragraph 4). Sitruk-Ware et al. further teach estrogen compounds at low doses such as 7.5 µg/day for prolonged release regimen in the treatment of urogenital atrophy (pg. 8, paragraph 1).

The Willhite and Sitruk-Ware et al. references are as discussed above and incorporated by reference herein. However, Sitruk-Ware and Willhite do not teach the use of an estrogenic component such as estetrol.

Spicer et al. teach preparations for use for extended period of time comprising gonadotropins (GnRH) and estrogenic compounds (see col. 1, lines 9-11). Spicer et al. further teach the addition of estrogenic steroids for counteracting the possibility of side effects such as urogenital atrophy which may develop during prolonged therapy (col. 3, lines 25-46). Estrogenic steroids such as estetrol may be employed in the composition for a short term administration on the order of about 5 to 20 days and formulated for vaginal delivery (instant claims 26 and 28; col. 5, lines 49-53, and 60, and col. 6, line 68). These compositions can further include a carrier vehicle known for controlled release (see col. 7, lines 1-5).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the composition of Spicer et al. in view of their efficacy in combating urogenital atrophy since Willhite et al. teach that vaginal dryness is also known as urogenital atrophy. Moreover, one of ordinary skill in the art would have found it obvious to formulate the composition of Spicer et al. as a vaginal cream since Sitruk-Ware et al. teach that creams are conventional formulations in the treatment of vaginal atrophy. Thus, given that Sitruk-Ware et al. teach a method of treating vaginal dryness or urogenital atrophy, and Spicer et al. teach the use of estrogenic compound

such as estetrol for combating urogenital atrophy, and Willhite et al. teach that urogenital atrophy is vaginal dryness, one of ordinary skill would have been motivated to utilize the composition of Spicer et al. at a dose of at least 7.5 µg/day of an estrogenic compound as taught by Spicer et al. to treat vaginal dryness as disclosed by Sitruk-Ware et al. and use estetrol as the preferred compound in light of the disclosure of Spicer et al. with the reasonable expectation of providing a method that is efficacious in counteracting GnRH side effects including vaginal dryness.

Claim 20 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Sitruk-Ware et al. (Schweiz. Rundsch. Med. Praxis, 1997, Vol. 86, No. 33, pgs. 1-13, English Translation) in view of Spicer (U.S. 5,211,952, previously cited) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480, previously cited) as applied to claims 18-19, 24, 26, 28, and 32 and in further view of Younglai et al. (J. of Clinical Endocrinology and Metabolism, 1968, Volume 28, Issue 11, pgs. 1611-1617), previously cited.

The Sitruk-Ware and Willhite references are as discussed above and incorporated by reference herein. However, Sitruk-Ware and Willhite do not teach the precursors of the estrogenic compound of claim 28 containing acyl radical moieties.

Younglai et al. teach that estetrol (i.e. E4) has many precursors (see pg. 1617, figure 2). In fact, Younglai et al. teach 15- α -hydroxyandrostenedione or

Art Unit: 1617

dehydroxyandrostenedione as precursors of E4 and containing acyl moiety group, both of which contain an acyl group moiety (instant claim 20; pg. 1616, right col.).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious utilize dehydroxyandrostenedione and 15- α -hydroxyandrostenedione as precursors of E4 since Younglai et al. teach them as precursors of E4. Given the teachings of Sitruk-Ware, Willhite, and Younglai, one of ordinary skill would have been motivated to utilize estetrol derived from 15- α -hydroxyandrostenedione or dehydroxyandrostenedione to treat vaginal dryness with the reasonable expectation of providing a method that is efficacious in counteracting GnRH side effects including vaginal dryness.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

08/15/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617